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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,299	09/16/2003	Hidenari Sakaguchi	P24222	1782

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EXAMINER

ROBERTS, LEZAH

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 02/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/662,299	Applicant(s) SAKAGUCHI ET AL.	
	Examiner Lezah W. Roberts	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 Jan 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 6, 12, 17 and 23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-11, 13-16, 18-22 and 24 is/are rejected.
- 7) ☒ Claim(s) 2 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>12 March 2004</u> . | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

The office recognizes the amendment filed January 10, 2006 for the election of species:

- a) free radical scavenger – catalase;
- b) base – microcrystalline wax; and
- c) emulsifier – sorbitan fatty acid esters.

This election is with traverse.

Claims 1-5, 7-11, 13-16, 18-22 and 24 will be examined on the merits. Claims 6, 12, 17 and 23 are withdrawn from consideration.

Claims

Objections

Claim 2 is objected to because of the following informalities: the letter “a” should be changed to the word “an” before the word “enzyme-based antioxidation” and the word “an” should be replaced with “a” before “non-enzyme antioxidation material”.

Appropriate correction is required.

Claim Rejections - 35 USC § 102 - Anticipation

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1) Claims 1-5, 7-11, 13-16, 18-22 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakano (EP 0273579).

Nakano teaches compositions for the treatment of alveolar pyorrhea. These compositions include a solution, a tablet, chewing gum, paste or powder (page 3, paragraph 4). The compositions comprise components such as superoxide dismutase, white Vaseline, and polyoxyethylene (20) sorbitan monostearate (Example 7); a free radical scavenger, a base and an emulsifier, respectively, that encompass the instant claims. The compositions may also include catalase. It is advantageous to add catalase to the compositions in order to remove hydrogen peroxide and hypochlorite. Catalase is also commercially available (page 3, lines 7-14). The reference clearly anticipates the composition of the instant claims. The intended use of the radical comprising compositions carries no weight in determining the patentability of the instant claims because the compositions disclosed by the reference comprise substantially the same compounds, i.e., superoxide dismutase, white Vaseline and polyoxyethylene (20) sorbitan monostearate as disclosed in example 7, are substantially the same as the compositions disclosed and claimed by the Applicant. Accordingly, in regards to the intended use claims 7, 8, 13-16, 18-22 and 24, one would have reasonably expected that the compositions of the reference would be able to protect gingival and oral mucosa against tooth bleaching agents, as the applicant's compositions can, since the

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compositions of the reference and the compositions of the instant claims are substantially the same.

2) Claims 1-5, 7-11, 13-16, 18-22 and 24 rejected under 35 U.S.C. 102(b) as being anticipated by Fujii et al. (EP 1 281 398 international publication WO 01/085156, 11-2001).

Fujii et al. teaches compositions comprising an oxidized coenzyme Q for dermal application. The compositions may also comprise antioxidants such as superoxide dismutase, catalase, glutathione peroxidase, and glutathione reductase (paragraph 0028). Other conventional cosmetic or skin health care products are added to the compositions such as waxes and emulsifiers (paragraph 0032). In one disclosed formulation, composition comprises of microcrystalline wax (a base), glycerol sorbitan fatty acid ester (an emulsifier) and Coenzyme Q₁₀ (the antioxidant) (example 2). This encompasses the instant claims. The compositions may be used as lipsticks and lip creams (paragraph 0031), therefore it would reasonably be concluded that they are not toxic if consumed or are on the teeth or gums. The intended use of the Coenzyme Q₁₀ comprising compositions carries no weight in determining the patentability of the instant claims because the compositions disclosed by the reference comprise substantially the same compounds, i.e., microcrystalline wax, glycerol sorbitan fatty acid ester and Coenzyme Q₁₀, are substantially the same as the compositions disclosed and claimed by the Applicant. Accordingly, in regards to the intended use claims 7, 8, 13-16, 18-22 and 24, one would have reasonably expected that the compositions of the reference

would be able to protect gingival and oral mucosa against tooth bleaching agents, because lipsticks and lip creams tend to get on the teeth and gums, as the applicant's compositions can, since the compositions of the reference and the compositions of the instant claims are substantially the same.

3) Claims 1-3, 5, 7-9, 11, 13-14, 16, 18-20, 22 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Kalvinsh et al. (EP 0 781 554).

Kalvinsh et al. discloses compositions to treat disease caused by a free hydroxyl radical. The reference discloses superoxide radicals and hydrogen peroxide are scavenged by enzymes *in vivo*. The enzymes scavengers for hydrogen peroxide are catalase and peroxidase (page 2, lines 15-19). The compositions of the disclosed inventions comprise betaines as hydroxyl radical scavengers, a non-enzyme antioxidant. The compositions also may comprise compounds such as polyoxyethylene sorbitan fatty acid esters (as encompassed in claims 4 and 10), polyethylene glycol (page 4, lines 38-52), liquid paraffin, white petrolatum, bleached bees wax and paraffin (page 5, lines 12-16). One composition comprises glycinebetaine hydrochloride as the scavenger, microcrystalline cellulose and hydroxypropylcellulose (example 1). This composition encompasses claims 1, 2, 3, 5, 9 and 11. The compositions may be in the form of an oral composition (page 4, lines 25-29). The intended use of the betaine comprising compositions carries no weight in determining the patentability of the instant claims because the compositions disclosed by the reference comprise substantially the same compounds, i.e., glycinebetaine hydrochloride, microcrystalline cellulose and

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hydroxypropylcellulose, are substantially the same as the compositions disclosed and claimed by the Applicant. Accordingly, in regards to the intended use claims 7, 8, 13-16, 18-22 and 24, one would have reasonably expected that the compositions of the reference would be able to protect gingival and oral mucosa against tooth bleaching agents, as the applicant's compositions can, since the compositions of the reference and the compositions of the instant claims are substantially the same.

Claims 1-5, 7-11, 13-16, 18-22 and 24 are rejected.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass
Primary Examiner
Art Unit 1614



Lezah Roberts
Patent Examiner
Art Unit 1614

